K081932

JAN 22 2009

510(k) Summary

General Information

Submitters Name/Address:	Hygeia Medical, Inc 6353 Corte del Abeto, Suite 102 Carlsbad, CA 92011
Establishment Registration Number:	3006774448
Contact Person:	Jasper Benke
Phone Number:	(760) 918-0339
Date Prepared:	June 30, 2008

Device Description

Trade Name:	EnDeare™ Breast Pump
Generic/Common Name:	Breast Pump and Accessories
Classification Name	Powered Breast Pump (21 CFR 884 5160, Product Code HGX)

Predicate Device Information

Medela Lactina® Breastpump (K875300)

Medela Pump-in-Style® (K950750)

Ameda Purely Yours (K973501))

Product Description

The product is a powered breast pump with accessories that is used to express and collect milk from the breasts of lactating women

Intended Use

The EnDeare™ Breast Pump is indicated to express and collect milk from the breasts of lactating women

Substantial Equivalence

In establishing substantial equivalence to the predicate device, Hygeia Medical evaluated the indications for use, materials, technology, product specifications, and energy requirements of the system Performance testing has been completed to demonstrate the safe and effective use of the EnDeare™ Breast Pump for the intended use

Summary of Safety and Effectiveness

Performance testing and device comparison demonstrate that the subject device is substantially equivalent to the predicate device, and is safe and effective for the intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2009

Mr Jasper Benke
Vice President, Quality and Regulatory Affairs
Hygeia Medical, Inc
6353 Del Abeto, Suite 102
CARLSBAD CA 92011

Re K081932
Trade/Device Name EnDeare™ Breast Pump
Regulation Number. 21 CFR §884 5160
Regulation Name Powered breast pump
Regulatory Class II
Product Code HGX
Dated December 3, 2008
Received December 5, 2008

Dear Mr Benke

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801, good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter

21 CFR 876 xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884 xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892 xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry suppot/index html

Sincerely yours,

Janine M Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K081932

Device Name EnDeare™ Breast Pump

Indications for Use

The EnDeare™ Breast Pump is indicated to express and collect milk from the breasts of lactating women

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081932